Week of 18 June 18

- Brian dogged registrants about 90-days response submissions
- Monica Wait confirmed that TGAI is fine for the 3 aquatic plant test studies
- Handoff from Brian to me
    - There is a lot of confusion about cost sharing between registrants

Week of 25 June 18

- Viance claimed a repack exemption

Week of 16 July 18

- I dug into the cost sharing situation

Week of 23 July 18

- 7/26: Cost sharing alliances cemented (see [HYPERLINK "file:///F:\\Chemicals\\Tebuconazole\\Cost%20Sharing%20Alliances\\Updated%20Tebuconazole%20Cost%20Sharing%2026%20Jul%2018.xlsx"])
    - Email came in from the ~~Tide~~ United Phosphorous Inc groups
    - There are now 2 group, the ~~Tide~~ United Phosphorous Inc and the Bayer
        - It is unclear to which ADAMA Ivitra belongs
            - ~~**Perhaps they need an email**~~
                - I figured it out; they are the same company as Viance
- Many registrants (the non-technical ones) are claiming a repack exemption. How do we grant that?

- 7/26: The ~~Tide~~ UPI alliance (Janelle Kay) submitted 3 study proposals and requested a meeting for the week of Aug 13
    - SS-1196; Chronic sediment – *Leptochirus*
    - SS-1197; Chronic sediment – *Hyalella*
    - SS-1197; Chronic sediment - *Chironomus*
    - ~~**The studies will need to have MRIDs and be beaned**~~
        - Done 8/9
    - The meeting is set for Aug 14 @ 11am (see meeting notes tab above)

Week of 30 July 18

- 7/31: The Bayer alliance request and extension for three studies and to change for avian acute tox to dietary
    - The extensions are within the timeline, so we can grant them
    - Will I need to bean EFED for the study change request?
        - yes
- 7/31: I emailed Banza Djapao in ITRMD (?) about getting MRIDs for the proposals submitted by ~~Tide~~ UPI alliance
    - 7/31: He said he'd get back to me
    - 8/1: he helped me to assign MRIDs
        - ~~**I will have to bean the protocols to EFED**~~ done 8/9
- 7/31: email AD about granting repack exemptions and if that need a memo or what
    - ~~**No response yet**~~ (see email 6/8)
- 8/1: I emailed EFED and AD about the Bayer extension request and guideline change
    - ~~**No response yet**~~ (emails 3/8 and 6/8)

- 8/1: I emailed Monica Wait of EFED about the study proposals submitted by Tide et al
  - ~~**No response yet**~~ (email 3/8)

Week of 6 Aug 18

- 8/6:
  - On 2/8 Janelle Kay of the ~~Tide~~ UPI alliance asked if the EPA still requires submission of protocols for chronic adult honey bee or chronic larval provided the protocol follows OECD guidelines. ~~**Will have to get back to her on that and then maybe tell the Bayer folks**~~
    - See Nicole's email to Janelle Kay 6 Aug 18
  - On 3/8 Monica Wait of EFED informed me
    - that Amy Blankenship had been replaced by Michael Lowit on the EFED team;
    - that EFED has no objection to extending the deadlines, per the 8/1 Bayer request; and
    - that Michael Lowit would have to respond to the question of changing the dietary test with an acute test (RE Bayer ext request)
      - ~~**No response yet**~~
        - He pushed back on letting them change acute for dietary
  - On 3/8 Monica Wait also asked what date we would have in mind instead for the protocol review (see
    - ~~**I will have to respond to her**~~. I asked Nicole, and she said that she would get back to me
      - She said that the end of September (6 weeks, rather than the usual 8)
        - See notes from 7/26
    - Kevin sent me a confusing note related to this (6/8) and I haven't been able to pin him down on it; ~~**will have to do that**~~
      - He was confused
  - Dan Halper of AD responded that he would get back to me RE the repack exemptions
  - Michael Lowit emailed and wants to push back on changing the acute for the dietary study (see ~~tide~~ UPI request)
    - I conferred with Nicole and updated my draft of our response the extension request to include this pushback
- 8/7: Barry O'Keefe from EFED called trying to figure out what Janelle Kay wants to know about the DFR/TTF studies in the meeting on Aug 14th, since any information that could be needed is online. I sent Kay an email asking for details
  - ~~**No response yet**~~
    - 9/8: Kay responded (see email from today), sort of a punt. I emailed Barry to follow-up
      - ~~**No response from Barry yet**~~ (response on 13 aug)
      - ~~**I will have to respond to Kay after Barry responds**~~ (never responded directly to this--was moot)
- 8/8:
  - I have figured out, by reading the study protocols from J Kay, that the ~~Tide~~ UPI alliance is actually being led by United Phosphorous, and not Tide, However, they seem not to have submitted a 90-Days Response
    - ~~**Find UP's 90-Days Response**~~
      - Fond in Brian Kettl's hard copy notes
  - I tried to upload the studies that Bonza got MIRDs for, but was unable to do so; Matt and Shanta suggested that this is ITRMD's responsibility. I emailed Bonza and asked for help
    - ~~**No response yet**~~
    - Bonza uploaded the documents

- Spoke with Kevin, he thought that they were study results not protocols, so that's what that email was about
  - He suggested that we could ask EFED to get these reviewed at the end of Sept. so that the registrant would have a year to complete the studies
    - ~~**Email Monica Wait and let her know the situation with the upload to documentum and the timeline**~~
    - ~~**Bean protocols to EFED**~~
      - Done 8/9

- 8/9:
  - Nicole suggested that I could read up on bird toxicity (see email from today) and that would help us to decide the response to Bayer about switching from acute to dietary (see Bayer's extension request from 7/31)
    - ~~**Research the stuff**~~ done 8/10
  - Nicole also had suggestion for the response memo to the extension request (7/31)
    - ~~**Review comments**~~ done 8/10
- 8/10:
  - Accepted Nicole's comments on Bayer memo; current draft is Draft 3 nz jw nz jw
  - Did the research for about acute tox to passerines (see email 8/9)
  - Emailed Snyderman about how to associate the protocols submitted by U Phosphorous on behalf of the consortium with the other companies in the consortium
    - ~~**No response yet**~~
      - We will meet Monday to discuss
        - 8/13: he showed me how

Week of 13 Aug 18

- 8/13:
  - I heard from Tom Moriarty and Barry O'Keefe about the DFR/TTR question (see multiple emails)
    - Dug into the justification for the DFR/TTR requirements in the Scooping Doc and emailed the team and reviewed some REIs
    - I invited RD reps to the meeting--it seems that Bayer has satisfied the TFR but not UPI, so RD will be useful for knowing what is what and who can know what RE: data sand cost sharing
  - Kevin suggested that because of the Deliberative Process / Ex. 5 Deliberative Process / Ex. 5
    - Set up a meeting with EFED for next week
      - Meeting set for 10 am 8/21
  - Dan suggested the repack exemptions were mine to coordinate with RD
    - Nicole said we can Deliberative Process / Ex. 5 **Deliberative Process / Ex. 5**
      - **Email Dan**
- 8/14:
  - Registrant meeting today with Tebuconazole Taskforce headed by UPI
    - See meeting notes
    - After meeting Barry O'Keefe wanted to clarify what he had told the reps about the number of study sites for DFR and TTR
      - ~~**Call Barry with Nicole**~~

        - He came by and we spoke in person (below)
    - **Email TF (Janelle Kay and Dave Olson)**
- 8/15:
    - Barry, Nicole, and I spoke regarding UPI's question of sites for the TTR study. UPI would like to submit data from fewer than 3 sites/crop (in this case, wheat and peanuts) and use EU data to satisfy the requirement
        - In the meeting, Barry sort of let on that we will accept anything and work with the registrant as best we can
        - After the meeting, Laura Bacon told Barry (I was not present) that it is best to ask for 3 sites/crop and get justification for anything less from the registrant
        - Later, Nicole spoke to Tom Moriarty (the branch chief in HED) on the phone and he said that what really matters is getting 3 sites total, not per crop
        - I don't know where this 3 is coming from. Janelle Kay seemed to know it as well. The published guideline does not specify any numbers, just that a diversity of sites be sampled.
        - **I will have to email Tom, Barry, Laura, and Nicole (CC) about this**
            - Nicole will forward answer to UPI as I will be on vacation on Monday
    - Philip Ross of OGC got in touch. There have been petitions related to the 90-Days Responses and the GDCIs. He would like to see a bunch of documents (see email 8/15)
        - ~~**Respond to Phillip**~~
            - Done 8/15
- 8/16:
    - Phillip Ross of OGC responded. He is satisfied with what I sent him, but may ask for more information later
    - I emailed Tom Moriarty, Barry Okeefe, and Laura Bacon of EFED for clarity on the language that I plan to send to Janelle Kay about the number of study sites for the TTR study.
        - ~~**No response yet**~~
            - Phil asked for several formatting changes to the notes that I shared and I made them

*****Updates since 16 Aug 2018*****

Week of 20 Aug

- 8/21:
  - Several emails in my inbox from Friday and Monday, when I was out of the office:
    - From: Jessica Fernandez (Bayer): what's the status on the extension request and request to change the passerine acute for dietary study, from 2 weeks (I think) ago?
      - We have a meeting on that today
      - **Respond**
    - From: Michael Lowie (EFED): Happy to discuss the acute vs oral studies at a meeting
      - I reminded him of my outstanding meeting request.
    - From: Janelle Kay (Pyxis/UPI): Asking for clarification RE: sites and crops for the TTR studies, "...proposing 2 crops (peanuts and wheat) in a total of 3 sites."
      - Forwarded to HED
      - ~~**Respond to Janelle**~~
        - Done 8/21
    - From: Tom Moriarty (HED): Will get back to me RE: the language of the advisory to Janelle/UPI about the number of sites vs crops for the TTR studies
      - I already sent that advisory out, based on a conversation with Nicole about a phone call between her and Tom about the language
      - I responded explaining this and then forwarded Janelle's response (see above)
        - **No response yet**
    - From: Phillip Ross (OGC): A response to non-work-related email about bridges of Pgh
  - Meeting with EFED
    - Bayer request to do dietary vs acute toxicity study
      -
      -

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

- I will:
  - Draft a memo for Bayer granting extensions, Deliberative Process / Ex. 5
    - ~~Send to EFED for review~~ done 8/21
    - ~~Get signed and sent to Jessica Fernandez of Bayer~~ done 8/27
  - ~~Contact Janelle Kay of the UPI group~~ done 8/21
    - TGAI vs TEP on terrestrial plants
    - Preemptive email about birds
      - See response 8/22

- 8/22:
  - Response from Janelle Kay:
    - The TEP/TGAI thing was just a typo
    - Acknowledged the guidance on birds
      - Response passed to EFED
  - EFED responded with comments on my memo (8/21) to Bayer and I incorporated them into a memo
    - Memo sent to Kevin on 8/22
      - ~~No response~~ reviewed and signed 8/27

- 8/23:
  - Drafted a cover letter for the memo to Bayer (8/22) and sent to Kevin
    - ~~No response~~ reviewed and signed 8/27; cover letter not needed

- 8/24
  - Emailed Nicole Zinn about each of my chemicals' status, including tebuconazole

Week of 27 Aug 18

- 8/27
  - Transmitted signed memo to Bayer RE: Request for a Deadline Extension for Tebuconazole

Week of 3 Sep 18

- 9/4
  - Jessica Fernandez responded to the extension request (see 9/4 email)
    - Is going to try to submit more inform to support request for dietary in lieu of acute oral test
    - Wants to call about prothioconazole, another triazole
      - ~~Find out who is in charge of this, PRD, AD, RD?~~
        - Done 9/4
        - Good news, it's Tiffany Green's and Nicole is the TL; Brian had it before Tiffany
        - Kevin suggests digging up any memo we may have sent granting said permission
      - It is probably someone else's responsibility to oversee this call, b/c it's prothioconazole
      - Jessica shared her minutes from a meeting about prothioconazole that she had with Brian, who was overseeing it at the time

- Okay, I spoke with Brian Kettl (who managed both prothioconazole and tebuconazole before) and Tiffany. Neither can find a memo to support the decision on prothioconazole RE: the dietary vs the acute oral tests. Brian suspects none was written, as this appears to have been brought up in a meeting, orally. I suspect the same, based on the meeting notes shared by Jessica in her email (see email 9/4)
  - I have now reached out to the EFED team members whom Jessica's show to have been present at the meeting in question to ask for their recollection of the evens and for any memos or documents that may have been written
    - ~~**No response, yet**~~ see email response from Thomas Seeger 9/5

- 9/5:
  - Per suggestion after conversation with Nicole this morning, emailed EFED tebuconazole team from meeting on 8/21/18 explaining situation and asking them to talk to the prothioconazole
    - Response form Michael Lowit saying that he would follow-up with prothioconazole team, but that in other triconazole cases, they have deigned similar acute vs dietary requests
      - This gives us something to go back to Bayer with
  - Thomas Seeger of the EFED team for prothioconazole got back to me explaining how the decision to move to the dietary study was made. The email is long, so see it directly.
    - I will set up a call with Jessica later this week or Monday for some time in the future
      - 9/13: Still haven't set up call or responded--too busy with PIDs

- 9/13:
  - Yesterday, an email from Janelle Kay (CC: Dave Olson), 2:21 PM:
    - Requesting extension for several studies (8501400, 850.4150, 875.2100, 850.2100, 850.3020, 850.4500, 850.4550, 850.6100, SS-1111, -1112, -1113, and -1114), which we granted orally in meeting on 14 Aug
    - Also says that it is waiting on the Agency for more info about the Foliar Dislodgeable Residue Dissipation study sites
      - I thought that we had addressed this (see email Aug 17)
    - Asks for deferment on higher tier pollinator data extension until tier 1 data is in
      - We did this for Bayer, no?
  - To do in response:
    - Confirm that the studies are the right studies--there was a typo on one of her slides from the Aug 14 meeting
    - Consult on FDR studies
      - Looks like UPI proposed
        - Peanuts in SE USA, such as VA, NC, GA, or SC
        - Wheat in NW, such as WA, OR or ID
        - Wheat in W, such as CA, AZ, NM or TX
      - Which I forwarded to HED and did not receive a response
    - Confirm timeline of studies and if that moves us forward--PID: FY 21 Q4 (Sept 21)

GLDN	Name	Correct?	Original Date	Requested Date	Bayer Ext?
850.4100	Seedling Emergence and Seedling Growth	Y	9/30/18	2/28/19	
850.4150	Vegetative Vigor	Y	9/30/18	2/28/19	

875.2100	Foliar Dislodgeable Residue Dissipation[3]	Y	9/30/18	12/31/19	
850.2100	Avian Acute Oral Toxicity Test	Y	9/30/18	6/30/19	Y
850.3020	Honey Bee Acute Contact Toxicity	Y	9/30/18	12/31/19	
850.4500	Algal Toxicity	Y	9/30/18	1/31/19	Y
850.4550	Cyanobacteria (Anabaena flos-aquae) Toxicity	Y	9/30/18	1/31/19	Y
850.6100	Environmental Chemistry Methods and Associated Independent Laboratory Validation	Y	9/30/18	12/31/18 (ECM) 1/31/19 (ILV)	
SS-1311	Honey Bee Adult Acute Oral Toxicity	Y	9/30/18	21/31/18	
SS-1312	Honey Bee Larvae Acute Oral Toxicity	Y	9/30/18	21/31/18	
SS-1313	Honey Bee Adult Chronic Oral Toxicity	Y	9/30/18	21/31/18	
SS-1314	Honey Bee Larvae Chronic Oral Toxicity	Y	9/30/18	21/31/18	

Week of 17 Sept 2018

- 9/17:
  - Bayer consortium
    - Several submissions from Friday
      - 1-year progress report
        - **Does this need a bean?**
          - ~~Yes, looks like they were beaned in the Reg Review Management tab of PRISM, rather than the DCI Management tab~~
            - This note belongs elsewhere--at some point I thought that some studies had not been beaned, but they were; possibly this related to acetamiprid
      - The data for 8 studies due Friday 9/14, and 3 voluntary submissions
        - Submitted guidelines: 850.4100 (MRID 50670803), 835.4150 (50670804), 875.2100 (50670809, -10, -11), 850.3020 (50533001), 850.3030 (50520601) 850.3040 (50520601) 850.4500 (50533002; see note in memo), 850.6100 (50670805, -6), SS-1311 thru SS-1316 (see MRIDS)

MRID	GLDN	Title	Notes	Bean DP	Email Date
50670804	835.4150	Vegetative Vigor	Fate, typo (850.4150)	448897	9/18
50670803	850.4100	Seedling Emergence and Seedling Growth	Eco	448895	9/18

50670805	850.6100	Environmental Chemistry Methods and ILV	Fate	448897	9/18
50670806	850.6100	Same	Fate	Same	9/18
50670809	875.2100	Foliar dislodgeable residue dissipation	HED	448898	9/18
50670810	875.2100	Same	HED	Same	9/18
50670811	875.2100	Same	HED	Same	9/18
50670808	SS-1316	Field trial of residues in pollen and nectar	Eco	448895	9/18

        - ~~**Beans, beans, beans**~~ done 9/18
    - UPI consortium
        - I have drafted a memo granting their extension request, it includes language letting them go with their proposed study sites for the DFR/TTR studies
    - Sent an email to Nicole with status updates (4:41 PM)
- 9/18:
    - Sent the emails with the bean sheets to their respective teams in the science divisions
    - Tried to create beans for the voluntary submissions referenced in Jessica's cover letter from the submission, but was unable to find the documents in the system
        - The voluntary submission are not reflected in the table above from 9/17
        - The MRIDs are 50670801, 50670802, and 50670807
        - Matt suggests that they may show up after a few days; I will check back in on Friday, I guess
        - ~~**Bean voluntary submissions**~~ done 9/21
- 9/19:
    - Two emails from Monica Wait, today.
        - First: acknowledging receipt of beans
        - Second: A follow-up pointing out that MRIDs 50670805 and -06 (which are independent laboratory validations; ILVs) need to be accompanied by environmental chemistry methods (ECMs). See GLDN 850.6100
            - I responded that I would ask Jessica
            - Sent email to Jessica about the matter (3:41 PM)
    - Voluntary submissions (MRIDs 50670801, 50670802, and 50670807) have not appeared in Documentum
    - Response from Jessica: She will check with someone with more experience in digital uploads about the ECMs. She has been having trouble uploading the voluntary submissions, as well.
        - I told her to send courtesy copies of the voluntary submissions and I will try to upload them
- 9/20:
    - According to Jessica, the files are too big to be emailed and so she suggested using a file uploader to share the documents, whereby she would upload them to a server and then I would get a temporary login to the server to be able to retrieve them. Sounds fishy, but she says that she does it with RD all the time. I consulted with Nicole and Dana and they think that it's a bad idea. I told Jessica that she would have to email them or use CDX.
- 9/21:

- The voluntary submissions from Bayer came in

MRID	GLDN	Eco or Fate?	Notes	Bean	e-Mail Date
50681901	835.1230	Fate	Original MRID:	449009	9/21
50681902	835.1230	Fate	Original MRID:	449009	9/21
50681903	850.SUPP	Eco?	Original MRID:	449010	9/21

- To Do:
  - ~~Bean submissions~~
  - ~~Respond to Jessica~~

Week of 24 Sept 2018

- 9/24
  - I have a few things that I need to follow-up on for each of the cost sharing consortiums:
    - UPI Group;
      - Get extension memo comments from Nicole (see email to her on 9/17)
        - What about the number of study sites?
      - Bayer group
        - What about the avian tox thing?
  - Nicole got back to me on the UPI extension memo (email at 4:14 pm)
    - Per her comment track changes, I forwarded the memo of Tom Moriarty of HED (email at 4:48 pm) for comment
      - **No response yet**

Week of 1 oct 2018

- 10/1:
  - Email from Phil (received Fri 9/24 4:54 pm)
    - Wants an update to any actions taken on tebuconazole since he first looked into the petition in August
    - ~~See meeting notes under Phil Update 10/1~~
      - Phil did not respond to the meeting request; we rescheduled for tomorrow
  - I followed up with Tom Moriarty of HED about the UPI extension memo by phone, and then by email (sent 2:11 PM)
    - He will respond on Wednesday
- 10/2:
  - Phone conference with Phil and Nicole today to catch up on the situation
    - Might make sense to set up a meeting to discuss my notes in person
    - The petition
      - 8, all filed by Bayer
      - Phil will share his copies with us
      - Bayer v Tide, Rotam, Jiangsu, UPI, Willowood, Charda, Luxembourg, and Helm
      - Failed to comply with 3c2b
    - Send to Phil:
      - Memos requesting and granting any extensions and personal notes